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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,019	01/26/2001	Richard P. Harvey	00786-407001	2930

7590

09/27/2002

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EXAMINER

LIU, SAMUEL W

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 09/27/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,019

Applicant(s)

HARVEY ET AL.

Examiner

Samuel W Liu

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

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Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-14, drawn to an isolated polynucleotide.

Group II, claims 15-27, 54, 57 and 58, drawn to an isolated protein and a pharmaceutical composition comprising the protein.

Group III, claim 28, drawn to a method of modulating expression of *Csl* gene in a mammal comprising contacting the *Csl* gene with an agent..

Group IV, claim 29, drawn to a method of modulating functional activity of Csl protein comprising administering to a mammal an agent.

Group V, Claims 30 and 52, drawn to a method of modulating muscle cell function in a mammal comprising administering to said mammal an agent.

Group VI, Claims 31-33 and 55, drawn to a method of modulating muscle cell function in a mammal comprising administering to said mammal an isolated protein.

Group VII, Claims 34-36 and 56, drawn to a method of modulating muscle cell function in a mammal comprising administering to said mammal a polynucleotide.

Group VIII, Claims 37-39, drawn to a method of modulating muscle cell function in a mammal comprising administering to said mammal an isolated protein, which targets calcineurin-dependent signaling pathway.

Group IX, Claims 40-42, drawn to a method of modulating muscle cell function in a mammal comprising administering to said mammal a polynucleotide, which targets calcineurin-dependent signaling pathway.

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Group X, Claims 43-45, drawn to a method of modulating muscle cell function in a mammal comprising administering to said mammal an agent, which targets calcineurin-dependent signaling pathway.

Group XI, Claims 46, 50-51 and 53, drawn to a method of treating a disorder state comprising administering to a mammal an agent capable of regulating muscle cell function.

Group XII, claim 47, drawn to a method of treating a mammal an agent capable of regulating Csl protein activity.

Group XIII, claim 48, drawn to a method of treating a mammal a polypeptide.

Group XIV, claim 49, drawn to a method of treating a mammal a polynucleotide.

Group XV, claims 59 and 61-62, drawn to an antibody directed to a polypeptide.

Group XVI, claim 60, drawn to an antibody directed to a polynucleotide.

Group XVII, Claims 63-64, drawn to a method of detecting Csl protein using an antibody against Csl protein.

Group XVIII, Claims 63-64, drawn to a method of detecting Csl polynucleotide using an antibody against Csl polynucleotide.

Group XIX, Claim 65, drawn to a method of treating a disorder state comprising screening for Csl polypeptide.

Group XX, Claim 65, drawn to a method of treating a disorder state comprising screening for Csl polynucleotide.

Regardless of the elected group, applicant is required under 35 US 121 (1) to elect a single disease state from Claim 50 because each disease state differs in pharmacological mechanism, pathological state, therapeutic procedure and outcome of the treatment; and (2) to list all claims readable thereon including those subsequently added. The response to the election requirement should identify the claims readable thereon as directed to the elected invention.

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The inventions listed as Groups I - XX do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 1 of the instant application sets forth the common technical feature: an isolated polynucleotide encoding a protein that is expressed in heart muscles; this was known in the art prior to the effective filing date of the instant application. Accordingly, it does not constitute a special technical feature linking all claims, as defined by 37 CFR 1.475(a), as a single contribution over the art, and a holding of lack of unity is therefore proper.

Applicant is advised that in order for the response to this holding of lack of unity to be complete, it must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL

SWL

September 17, 2002

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600